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UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

KERYX BIOPHARMACEUTICALS, INC.,

Plaintiff,

-against-

PANION & BF BIOTECH, INC.,

Defendant.

ECF CASE 08 CIV. 3603 (DLC)

DEFENDANT'S ANSWER AND COUNTERCLAIMS

Defendant Panion & BF Biotech, Inc. ("Panion") responds to Plaintiff's Verified Complaint as follows:

# **NATURE OF THE ACTION**

1. States that the Verified Complaint speaks for itself with regard to the nature of the action, and denies all other allegations of paragraph 1 of the Verified Complaint except that there is a licensing agreement with limitations to the contractual rights of Keryx Biopharmaceuticals, Inc. ("Keryx"), that Keryx had commenced an action against Panion in this court, No. 07 Civ. 10376 (CSH) on November 16, 2007, that the Court (Judge Charles S. Haight, Jr.) granted Keryx's motion for preliminary injunctive relief and ordered Panion to consult with Keryx in good faith and that the action has been settled.

#### **PARTIES AND JURISDICTION**

- 2. States that the Verified Complaint speaks for itself, but if an answer is required,

  Defendant denies having sufficient information or knowledge to form a belief as
  to the truth of paragraph 2 of the Verified Complaint and therefore denies the
  same.
- 3. Admits the allegations contained in sentence 1 of paragraph 3. Denies the allegations contained in sentence 2 of paragraph 3 except Defendant maintains an office in Queens County, New York.
- 4. Admits.
- 5. Admits that the parties are of diverse citizenship but Defendant lacks sufficient information or knowledge to admit or deny the remaining allegations of paragraph 5 of the Verified Complaint and therefore denies the same.
- 6. Admits that the United States District Court for the Southern District of New York has jurisdiction for this action. Defendant denies the remaining allegations of paragraph 6.
- 7. Admits that the venue is proper pursuant to 28 U.S.C. § 1391(a).

#### BACKGROUND

- 8. States that Defendant lacks sufficient information or knowledge to admit or deny the allegations of paragraph 8 of the Verified Complaint and therefore denies the same.
- 9. Admits the allegations of paragraph 9 of the Verified Complaint except that the U.S. Patent is not "U.S. Patent No. 5,7753,706," but is U.S. Patent No. 5,753,706.
- 10. Admits.

- 11. Admits.
- 12. States that the Verified Complaint speaks for itself and admits that Keryx requested a modified API specification from Panion's API Specifications.

  Defendant denies Kerxy's characterization of Panion's API Specifications developed through extensive and continuous research as "historical experience."

  Defendant further denies that Panion's Specification should be called "prior" or that Keryx's proposed specification is "updated."
- 13. Admits the allegations in sentence 1 of paragraph 13 except Defendant denies that there was any formal approval of the draft. Admits the allegations in sentence 2 of paragraph 13 except the specification was approved pursuant to a release letter from Keryx. Denies the naming of "Joint Panion-Keryx Specification" and states that the Defendant lacks sufficient information or knowledge to form a belief as to the truth of the allegations in sentences 3 and 4 and therefore denies the same.
- 14. Admits receipt of the July 26, 2006 e-mail but denies that the matter was deemed "urgent." Admits that Panion introduced Keryx to BRI Biopharmaceutical Research, Inc. ("BRI"), but denies that BRI was only Panion's "previous API producer." Admits to the e-mails of August 28, 2006 and September 1, 2006. Denies all other allegations of paragraph 14.
- 15. Defendant admits that a quotation was e-mailed to Keryx, with a copy to Panion, on August 24, 2006. Defendant denies the allegations in sentence 4 of paragraph 15 which stated that Panion was aware of the impending production at BioVectra for Keryx. Defendant lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 15 and therefore denies the same.

- 16. Defendant lacks sufficient information or knowledge to admit or deny the allegations in paragraph 16 and therefore denies the same.
- 17. Admits except Defendant denies the allegations in sentences 3 and 4 of paragraph
  17 which stated that the actions against BRI and BioVectra were to seek
  injunctive relief to stop their activities "on behalf of Keryx."
- 18. Admits except that the actions taken were not in retaliation.
- 19. Admits.
- 20. Admits.
- 21. Admits.
- 22. Admits.
- 23. Admits.
- 24. Admits.
- 25. Admits except that Defendant denies the quotation was for API conforming to the prior Panion specifications.
- 26. Denies all allegations in paragraph 26 except that Panion had previously approved the modified specification pursuant to a release letter from Keryx. Defendant lacks sufficient information or knowledge to form a belief as to the truth of the alleged submission of the modified specification to the FDA and therefore denies the same.
- 27. Admits.
- 28. Denies except Defendant admits the allegations in sentence 1 of paragraph 28.
- 29. Admits.

- 30. Denies the allegations in paragraph 30 except on March 10, 2008 Panion responded to Keryx's e-mail.
- 31. Admits that Keryx made the statements in the e-mails except Defendant denies the allegations contained in paragraph 31.
- 32. Admits the allegations in sentence 1 of paragraph 32. Defendant denies the remaining allegations of paragraph 32.
- 33. Admits that Keryx made the statements in the e-mails except Defendant denies the allegations contained in paragraph 33.
- 34. Admits that Keryx made the statements in the e-mails except Defendant denies the allegations contained in paragraph 34. Defendant denies that Panion "failed to provide a price quotation."
- 35. Admits the allegations in paragraph 35 except Defendant denies declining to provide a binding price quote.

# (Breach of contract)

- 36. In response to paragraph 36, Defendant repeats and re-alleges Defendant's responses to paragraphs 1-35 of the Verified Complaint as though fully set forth herein.
- 37. Denies.
- 38. Denies.

# SECOND CAUSE OF ACTION (Breach of implied covenant of good faith and fair dealing)

- 39. In response to paragraph 39, Defendant repeats and re-alleges Defendant's responses to paragraphs 1-38 of the Verified Complaint as though fully set forth herein.
- 40. Admits.
- 41. Denies.
- 42. Denies.

# THIRD CAUSE OF ACTION (Declaratory judgment that Keryx may purchase API from an alternative supplier)

- 43. In response to paragraph 43, Defendant repeats and re-alleges Defendant's responses to paragraphs 1-42 of the Verified Complaint as though fully set forth herein.
- 44. Denies.

#### **FOURTH CAUSE OF ACTION**

### (Attorneys' and Expert Fees and Expenses)

- 45. In response to paragraph 45, Defendant repeats and re-alleges Defendant's responses to paragraphs 1-44 of the Verified Complaint as though fully set forth herein.
- 46. Denies.
- 47. Denies.

#### **AFFIRMATIVE DEFENSES**

# FIRST DEFENSE (Failure to State a Claim)

48. The Verified Complaint fails to state a cause of action upon which relief may be granted.

# **SECOND DEFENSE** (Unclean Hands)

49. Keryx's claims are barred by the equitable doctrine of unclean hands.

## THIRD DEFENSE (License, Consent, Waiver, Laches, Estoppel)

50. Keryx's claims are barred by license, consent, waiver, laches, and estoppel.

# FOURTH DEFENSE (Failure to Mitigate Damages)

51. Keryx's claims are barred by reason of plaintiff's failure to mitigate damages.

### FIFTH DEFENSE (Statute of Frauds)

52. Keryx's claims are barred by the Statute of Frauds.

# SIXTH DEFENSE (Lack of Justiciable Controversy)

53. There is no justiciable controversy with respect to Keryx's claims.

### SEVENTH DEFENSE (Jurisdictional Defect)

54. Keryx's claims are barred by lack of personal jurisdiction and insufficient service of process.

#### **COUNTERCLAIMS**

55. Counterclaimant Panion & BF Biotech, Inc. ("Panion") hereby alleges as follows:

#### **PARTIES**

- 56. Counterclaimant Panion is a corporation incorporated under the laws of Taiwan, and has its principal place of business therein, at 16F No. 3, Yuanqu Street, Nangang District, Taipei, Taiwan, and has an office in Flushing, New York.
- 57. Upon information and belief, Keryx Biopharmaceuticals, Inc. ("Keryx") is a corporation incorporated under the laws of the State of Delaware, and has its

principal, regular, and established place of business at 750 Lexington Avenue, New York, New York 10022.

#### **JURISDICTION AND VENUE**

- 58. Jurisdiction of this Court arises under 28 U.S.C. § 1332, because the amount in controversy exceeds \$75,000, exclusive of interest and costs, and the controversy is between a corporate entity located in New York State and a company located in a foreign state.
- 59. Venue is proper in this district under 28 U.S.C. § 1391(a).

# STATEMENT OF FACTS

# A. Background of Panion's Involvement with Ferric Citrate and the Development of Active Pharmaceutical Ingredient Technology (API)

- 60. Panion & BF Biotech, Inc. is a company headquartered in Taiwan which actively licenses, develops, and manufactures pharmaceutical and cosmetic products. The company is also active in the creation, design, and supervision of clinical trials for its pharmaceutical products.
- 61. On July 20, 2001 Panion licensed technology related to the compound ferric citrate from Dr. Chen Hsing Hsu (hereinafter "Dr. Hsu"). Dr. Hsu is the inventor and owner of the U.S. Patent No. 5,753,706 (hereinafter "Hsu patent"), issued May 19, 1998 and entitled "Methods for Treating Renal Failure." This patent claims a treatment for persons suffering from advanced end-stage kidney disease; the treatment involves the administration of ferric citrate to persons with that disease. While a United States patent has issued on this technology, patent applications have been filed in other foreign jurisdictions worldwide on the

- technology. Many of these applications are currently being prosecuted before their respective patent offices.
- 62. The Licensing Agreement executed between Panion and Dr. Hsu specifically encompassed development of an Oral Ferric Citrate Capsule by granting to Panion exclusive rights to make, use, and sell the inventions of the aforementioned U.S. patent and its Taiwanese equivalent outside of the People's Republic of China. Panion further possessed rights for Investigational New Drug (IND) application No. 52,868 for "Oral Ferric Citrate Capsule", which was filed with the United States Food and Drug Administration (FDA) for the purpose of gaining FDA approval for the treatment contained in the Hsu patent.
- Commercially available chemical grade ferric citrate lacks rigorous quality control and must be purified through the removal of numerous impurities. At the beginning of the development of this project, Panion initially attempted to buy commercially available chemical grade ferric citrate and to purify it to pharmaceutical grade. Because Panion's initial attempts were unsuccessful, Panion ultimately developed costlier and more demanding synthetic methods of purification. Panion has invested extensive research efforts in the synthetic process, including the use of highly purified raw starting materials and stringent process controls. The end result of the manufacturing process, i.e. the high quality pharmaceutical grade ferric citrate, is what is referred to by the parties as Active Pharmaceutical Ingredient (API). This API may thereafter be mixed with

- pharmaceutical grade fillers, and other pharmaceutical grade excipients, and put into capsules which will be administered to patients.
- 64. Since 2001 Panion has made extensive investments of time, resources, and expertise to establish a process for manufacturing ferric citrate into a Pharmaceutical Grade product in order to ensure pharmaceutical which meets the highest quality and safety standards. The processes involved are highly controlled, implicating not only the beginning raw starting materials, but dictating the result to be achieved at each step of the manufacturing and control processes for production of the API. Chemical grade ferric citrate obtained from commercial sources is not suited for human consumption and is merely tested for appearance, solubility, and elemental analysis; indeed only one quality test – for elemental analysis – is performed on chemical grade ferric citrate. There are no tests performed on chemical grade ferric citrate for impurities such as heavy metals, microbial contaminants, yeast, mold, and organic solvents. In contrast, the necessary control tests for Panion's API (hereafter, Panion API) include 20 separate Item Release Tests, with each Item Release Test consisting of many subtests. These control tests measure for various toxic substances such as heavy metals, microbial contamination, mold, yeast, and organic solvents, among others. They are used to strictly monitor and assure the quality of the Panion API and any resulting product as well as to guarantee the safety of patients. In addition to develop a stringently controlled process and specification, Panion also scaled up the process from laboratory scale up to multiple batches of 100 kilograms manufacturing, successfully, to ensure the consistency of good quality of API.

- 65. Independent of Keryx, Panion demonstrated the efficacy and dose-related increase in effect of the pharmaceutical grade ferric citrate in Phase II multi-national, multi-center clinical trials conducted in five (5) clinical sites in the United States and one (1) site in Taiwan. Also independent of Keryx, Panion demonstrated to the United States Food and Drug Administration the safety of ferric citrate (Panion's API) as compared to placebo capsules which contain no ferric citrate in its Phase II clinical study in the United States and Taiwan.
- Additionally, since 2001 Panion has actively worked with its contractors, BRI and BioVectra, to establish superior manufacturing processes for the Panion API. Indeed, BRI, located at 101-8898 Heather Street, Vancouver, British Columbia, Canada V6P 3S8, has been Panion's subcontractor for analytical services and Panion's primary provider of ferric citrate Panion API since December 20, 2001. Additionally, BioVectra DCL ("BioVectra"), located at 16 McCarville Street, Prince Edward Island, Canada C1E 2A6, is a subcontractor of BRI which has likewise been involved in the manufacture of ferric citrate for Panion.
- 67. Based in large part upon the pharmaceutical grade developments Panion has made to ferric citrate, Panion has previously been able to protect their proprietary information and know-how by filing three (3) patents for the technology.

#### **B.** The Panion-Keryx License Agreement

68. Panion and Keryx entered into a License Agreement dated November 7, 2005 (hereinafter "License Agreement"). Panion retained its rights to the Asia-Pacific region under the License Agreement with the exception of its rights to Japan, which have been licensed to Keryx.

- 69. Under the License Agreement Panion licensed to Keryx the right "to develop, have developed, make, have made, use, have used, offer to sell, sell, have sold, import and export the Compound and Product," such Compound being "ferric citrate", and such Product being "ferric citrate or any pharmaceutical product containing ferric citrate as an active ingredient, either alone or in combination with other active ingredients." The Compound in this context is referred to interchangeably by both parties in communications as the Panion Active Pharmaceutical Ingredient (API).
- 70. Pursuant to the License Agreement, Keryx is required to purchase the Panion API exclusively from Panion.
- 71. Pursuant to Section 7.7 of the License Agreement, Panion has the right to review and approve all aspects of the development and manufacture of API to be used by Keryx.

#### C. Keryx's Actions Respecting API Under the License Agreement

- 72. Panion introduced its manufacturing subcontractor, BRI, to Keryx for the purpose of providing Keryx with a better understanding of Panion's technology and manufacturing protocols but not for the purpose of permitting Keryx to manufacture API through Panion's own contractors in contravention of the provisions of the License Agreement.
- 73. In or about August 2006, Panion obtained from BRI a price quotation for the manufacture of the Panion API which was provided to Keryx. Keryx accepted Panion's initial quotation, and in August 2006 Panion thereafter informed Keryx that Panion would produce a formal quotation for 400 kg of the Panion API.

- 74. On August 24, 2006, as directed by Panion, Panion's subcontractor BRI forwarded to Keryx a quotation for manufacturing 400 kg ferric citrate. Subsequent to the BRI quotation, Keryx, without authorization from Panion, caused BRI and others to manufacture four (4) separate batches of purported API, only one of which met Panion's API specification. At no time has Keryx paid or offered to pay to Panion the 15% profit margin (over Panion's subcontractor's price for the API) to which Panion would have been entitled to under the License Agreement.
- 75. Subsequently, disagreements between the parties respecting the License Agreement including, *inter alia*, the API, resulted in a suit filed by Keryx and a countersuit filed by Panion on or about November of 2007 and on or about January of 2008 respectively.
- 76. Both parties agreed to settle this suit and countersuit and a Settlement Agreement and an Amended & Restated License Agreement between the parties was signed on or about March 14, 2008.

#### D. The Amended & Restated License Agreement

- 77. Section 7.7 of the original License Agreement remains unchanged and is carried over to the Amended & Restated License Agreement. Keryx is still obligated to purchase the API exclusively from Panion and pay Panion 15% over Panion's manufacturing and procurement cost.
- 78. Section 7.7 (b) of the Original and Amended & Restated License Agreement provides:

For the period commencing on the Effective Date and continuing for three (3) years following Registration in the United States (the "Exclusive Supply Period"), Licensee (and its Sublicensees) shall obtain their supply of the Clinical Supplies and of the Compound exclusively from Licensor. In consideration for such supply, Licensee shall provide compensation to Licensor at fifteen percent (15%) over Licensor's manufacturing and procurement cost. Notwithstanding the preceding two sentences, decisions and actions related to pharmaceutical development and manufacturing of the Clinical Supplies are subject to joint review and approval. During the Exclusive Supply Period, Licensee shall be entitled to engage an alternative supplier or suppliers of Clinical Supplies of the Compound provided that (i) Licensee has demonstrated to Licensor that the Clinical Supplies or the Compound subject to this Section 7.7(b) can be made available to Licensee by an alternative third-party supplier at a price that is more than 25% below what Licensor charges Licensee in accordance with this Section 7.7(b); and (ii) Licensor within sixty (60) days thereafter fails to meet the price offered by such alternative supplier.

# E. Keryx Is Breaching and Threatening to Breach the Amended & Restated License Agreement and Its Implied Duty of Good Faith and Fair Dealing and Is Acting in Bad Faith by Manufacturing a Dispute in an Attempt to End It's Contractual Obligations.

- 79. After the 2006 episode where Keryx ordered four (4) batches of API from Panion's subcontractors, three of which were not according to Panion's API specifications, Keryx requested modifications to Panion's API specifications to suit Keryx's research needs.
- 80. Despite Panion's disagreement and reluctance to approve Keryx's requested modifications to the Panion API specifications, Panion agreed to the modifications, but only pursuant to a release letter from Keryx which absolved Panion from any liability arising from the Keryx changes to the Panion API specifications (hereafter the Modified API).
- 81. While litigation between the two companies ensued, the two companies continued to maintain their working relationships. In a December 14, 2007 e-mail, Keryx

- expressed its intention to order 1,000 kg of the Modified API in the coming months with delivery to begin June 2008.
- 82. On December 21, 2007, Panion replied by e-mail that the price for the API is the same formal price quoted in the August 21, 2006 quote from Panion's subcontractor. Panion also stated that it would write up a formal quotation upon receipt of Keryx's formal purchase order.
- 83. In the ensuing three (3) months, Keryx was inconsistent about whether or not it had sent a formal request for API. Given Panion's prior experience with Keryx, ordering directly from Panion's subcontractors and bypassing Panion, Panion insisted upon receiving a formal purchase order first.
- 84. On February 12, 2008, Keryx sent a "formal request" letter by fax (dated February 7, 2008) and e-mail requesting a "firm price quotation" for 600-800 kg of the Modified API for delivery now arbitrarily set by Keryx for May 2008.
- 85. On February 13, 2008 Panion replied to Keryx in a letter acknowledging Keryx's "firm purchase order," confirmed that it was seeking a formal quotation from its subcontractors and would respond once Panion heard from them. To begin the formal purchase order process, Panion attached a draft API Supply Agreement for Keryx to review which included essential terms upon which the parties had to reach agreement, including, but not limited to: method and date(s) of delivery; purchase quantity; terms and conditions of sale; price; upfront and balance payment terms and timing; warranties; and quality specifications.
- 86. In a February 28, 2008 e-mail, Keryx thanked Panion for "undertaking to provide us with a formal quotation as soon as you hear from your subcontractor." But

Keryx rejected the API Supply Agreement solely on the basis it allegedly was a long term agreement, without attempting to negotiate any terms and conditions for the supply of API. Keryx further insisted again on receiving a firm price quote, and, contrary to Keryx's February 7, 2008 letter, Keryx now claimed that it had "not yet placed a formal purchase order" for API.

- 87. In a March 10, 2008 e-mail, Panion again insisted that the price was the same as the August 21, 2006 quote and that a formal quote would be drawn up upon receipt of a formal purchase order. Panion thanked Keryx for clarifying that the February 7, 2008 letter was **not** a "formal purchase order."
- 88. In a March 11, 2008 e-mail, Keryx changed its story again and insisted that the February 7, 2008 letter (sent February 12<sup>th</sup>) was a "formal request" and added the accusation that Panion's refusal to present a firm quote was holding up Keryx's development programs.
- 89. Given that Keryx has been inconsistent about whether or not it has sent a formal request, and the tone of its March 11, 2008 e-mail, Panion suggested in an e-mail dated March 27, 2008 that the parties "engage in a dialogue on non-agreed upon terms" that would govern Panion's supply of API to Keryx, rather than Keryx continuing to make unilateral demands.
- 90. In an e-mail dated April 5, 2008 (Saturday), Keryx's legal counsel insisted Panion send a "firm price quotation" by close of business on April 8, 2008 or Keryx will order directly from an alternative third party supplier.
- 91. On April 9, 2008, Panion replied in an e-mail that Panion has provided a quotation numerous times, that Keryx had not ordered from Panion since the

- License Agreement in November of 2005, that Panion did not like the threatening tone of the legal counsel's e-mail and unilateral demands and again suggested the parties engage in a dialogue.
- 92. On April 9, 2008, Keryx's legal counsel sent another e-mail insisting on a firm quote and gave Panion until April 10, 2008 to send the firm quote.
- 93. On April 15, 2008, Keryx filed this action but did not inform Panion that it had done so.
- 94. On April 21, 2008, Panion's Executive President sent an e-mail to Keryx's Chief Executive Officer (CEO) expressing a desire for the company heads to sit down and settle the ongoing dispute.
- 95. On May 6, 2008, Keryx's CEO responded by echoing the same sentiment.

  However, Keryx's CEO also requested a waiver of Section 7.7(b) of the Amended

  & Restated License Agreement signed on March 14, 2008.
- 96. At no time did Keryx alert Panion to the fact that a suit had been filed by Keryx against Panion until June 12, 2008, when Keryx's CEO sent an e-mail to Panion's Executive President notifying about the suit.
- 97. Since the beginning of the business relationship, Panion has been transparent, forthcoming and accommodating to Keryx to establish trust for a long term working relationship. To facilitate Keryx's development, Panion has introduced its own subcontractors to Keryx to understand the technology. Panion even consented to the Modified API upon Keryx's requests on February 17, 2007, pursuant to a release letter provided from Keryx.

- 98. In the License Agreement, Panion contracted with Keryx to be the exclusive supplier of the API for a price of 15% above Panion's manufacturing and procurement cost. No orders from Keryx resulted.
- 99. Keryx has worked with and has ordered directly from Panion's subcontractors and thus Keryx has at all times been fully aware of the price the subcontractors quoted and its obligation to pay 15% above that to Panion. The subcontractor's price quote is not a secret.
- 100. Panion had demonstrated that it was ready and willing to provide a formal quote based on mutually agreed terms. Panion also demonstrated its efforts to resolve the differences between the two companies by providing a draft API Supply Agreement for Keryx's comments and repeatedly offered discussion opportunities. Panion expressed reservations about the Modified API Specifications that Keryx preferred, but never refused to provide a quote for API made according to the Modified API Specifications.
- 101. To date, Keryx has yet to place any order for API with Panion or even discuss and arrive at mutually agreeable and necessary terms and conditions governing the ordering, manufacturing and supplying of API; rather Keryx now seeks to renege on its contractual obligations by ordering directly from a third party supplier.

#### **CLAIMS FOR RELIEF**

# FIRST CLAIM FOR RELIEF (Breach of Contract)

102. All preceding paragraphs are incorporated herein by reference.

- 103. Keryx is aware that if it has ordered or if it proceeds to order or obtains the API from an alternative supplier, it is in breach of the Amended & Restated License Agreement signed on March 14, 2008.
- 104. This breach constitutes a material breach of the Amended & Restated License Agreement.
- 105. As a result of this breach of contract, Panion has been damaged in an amount to be proven at trial.

# **SECOND CLAIM FOR RELIEF**(Anticipatory Repudiation of Contract Terms)

- 106. All preceding paragraphs are incorporated herein by reference.
- 107. Panion views Keryx's legal counsel's e-mail on April 5, 2008 as an anticipatory repudiation of the contract terms of the Amended & Restated License Agreement signed by both companies on March 14, 2008.
- 108. As a result of the anticipatory repudiation of the contract terms, Panion has been damaged in an amount to be proven at trial.

# THIRD CLAIM FOR RELIEF (Breach of Implied Duty of Good Faith and Fair Dealing)

- 109. All preceding paragraphs are incorporated herein by reference.
- 110. The Amended & Restated License Agreement imposed upon Keryx the duty of good faith and fair dealing and requires that Keryx deal honestly and fairly with Panion in the performance of the terms of the Amended & Restated License Agreement.
- 111. Keryx breached the duty of good faith and fair dealing by changing its story about whether or not it had sent a formal purchase order and manufacturing this dispute

- to make another attempt at by-passing Panion and ordering API directly from an alternative source in contravention of the Amended and Restated License Agreement signed on March 14, 2008.
- 112. Keryx also breached the duty of good faith and fair dealing by not informing Panion that a suit had been **filed** on April 15, 2008, less than three (3) business days after Keryx's last ultimatum (April 10, 2008), until June 12, 2008.
- 113. As a result of these breaches of the implied duty of good faith and fair dealing,
  Panion has been damaged in an amount to be proven at trial.

# FOURTH CLAIM FOR RELIEF (Breach of Fiduciary Duty)

- 114. All preceding paragraphs are incorporated herein by reference.
- 115. Keryx owes fiduciary duties to Panion because Panion and Keryx signed an Amended & Restated License Agreement, to do business in a manner in which Panion reposed trust and confidence in Keryx. Keryx's fiduciary duties to Panion include the duties of utmost care, good faith, loyalty, honesty, and full disclosure.
- 116. Keryx has breached these fiduciary duties by the acts and omissions described above detailing the attempts to avoid the terms of the Amended & Restated License Agreement as well as the failure to disclose to Panion that a suit had been filed.
- 117. As a result of Keryx's breach of its fiduciary duties, Panion has been damaged in an amount to be determined at trial.

#### **PRAYER FOR RELIEF**

WHEREFORE, Panion respectfully requests judgment:

- 118. (a) that Keryx materially breached the Amended & Restated License

  Agreement by ordering API from a third party or alternative supplier.
  - (b) that Keryx has anticipatorily repudiated the agreement by ordering or threatening to order API from a third party or alternative supplier.
  - (c) that Keryx has anticipatorily repudiated the Amended & Restated License Agreement by the filing of this lawsuit on April 15, 2008.
  - (d) that the anticipatory repudiation is a material breach of the Amended & Restated License Agreement.
  - (e) that the 90 days period in which Keryx could cure its breach began to run on the date Keryx filed this lawsuit, April 15, 2008.
  - (f) enjoining Keryx from purchasing Clinical Supplies of the Compound (ferric citrate) during the Exclusive Supply Period other than directly from Panion at a 15% over Panion's manufacturing and procurement cost.
  - (g) awarding monetary damages to Panion in the amount of at least one million dollars (\$1,000,000.00) or such greater amount to be proven at trial.
- 119. Awarding Panion its attorneys' fees and other legal costs in this case.
- 120. That the Court awards such further and other relief as it deems just and proper.

Dated: New York, New York July 4, 2008

# Respectfully submitted,

#### Of Counsel:

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